

**REMARKS**

Claims 1-50 are currently pending in the application. Claims 1 and 39 have been amended. No new matter has been added. Support for the amendment to claim 1 is found throughout the specification, and at least in Figures 1-3 and 9-11. Support for the amendment to claim 39 is found throughout the specification, and at least at page 3, lines 6-7 and 10-11, and page 7, lines 29-31. Claim 36 has been amended to correct a minor typographical error. Support for new claim 51 is found throughout the specification, and at least in Figures 1-3, 9-17, and 20-22, as well as at page 2, line 29 to page 3, line 2. Applicants respectfully assert that no new matter has been added and request reconsideration of the claims currently pending in the application.

Claims 30-38 and 50 are allowed. Claims 1-6, 9-11, 13-16, 18, 19, 21, 23, 26, 39, 42, 44 and 48 have been rejected. Claims 7, 8, 12, 17, 20, 22, 24, 25, 27-29, 40, 41, 43, 45-47 and 49 are objected to as being dependent upon a rejected base claim.

Applicants thank the Examiner for favorable consideration and allowance of claims 30-38 and 50.

On page 2 of the Office Action, claims 1-6, 9-11, 13, 15, 16, 18, 19, 21, 23, 26, and 39 are rejected under 35 U.S.C. §102 (b) as being anticipated by Duran (U.S. Patent No. 5,545,215). Applicants respectfully traverse the rejections.

On page 3 of the Office Action, claims 42 and 44 are rejected under 35 U.S.C. §102 (b) as being anticipated by Klostermeyer, et al.(U.S. Patent No. 5,891,195). Applicants respectfully traverse the rejections.

On page 3 of the Office Action, claim 48 is rejected under 35 U.S.C. §102 (b) as being anticipated by Fogarty, et al. (U.S. Patent No. 5,824,037). Applicants respectfully traverse the rejection.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Applicants respectfully submit that Duran does not teach every element of claim 1, and therefore fails to anticipate claims 1 and 39.

First, contrary to the Examiner's assertions, Applicants' expanded section is not disclosed by Duran's conduit. The bulges 48 of Duran's conduit 28 corresponding to the sinuses of Valsalva are expandable. (See *Duran*, Figs 8-9). This is distinctly different from Applicants' expanded section. (See Fig. 1).

Second, the expanded section extends from an end of the generally cylindrical section. "Section" is singular, indicating the presence of a single generally cylindrical section in the invention. Duran's open cage frame 20 is disposed between two cylindrical conduit sections. (See Fig. 9). Duran fails to disclose a single expanded section extending from an end of the single generally cylindrical section. Further, Duran does not set forth an expanded section terminating at an edge.

There are three distinct openings disposed around the circumference of Duran's open cage frame, adjacent frame openings being separated longitudinally by vertical struts 26. Each frame opening is configured and positioned to receive one of the three sinuses of Valsalva and the three corresponding "expandable" conduit sections covering the sinuses. Duran's open cage frame is disposed between two conduit sections that are generally cylindrical sections of equal diameter. (Fig. 9; p. 5, lines 52-56). As a result, there are two distinct and separate generally cylindrical sections in Duran; each such cylindrical section disposed adjacent to the relevant end of the open cage frame. Thus, there are six junctions between the "expandable" Duran sections and the adjacent cylindrical sections; each of the three "expandable" sections having a junction with the two adjacent cylindrical sections. (See, e.g., Figs 9-11). Duran fails to disclose the positioning of a junction between the expandable section and the generally cylindrical section as claimed by Applicants.

Since Duran does not disclose every element of the claimed invention, Duran fails to anticipate claim 1. Applicants respectfully request withdrawal of the rejection of claim 1 as being anticipated by Duran.

Dependent claims 2-6, 9-11, 13, 15, 18, 19, 21, 23 and 26 which depend from independent claim 1 were also rejected under 35 U.S.C. §102(b) as being anticipated by Duran. While Applicants do not acquiesce with the particular rejection to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claims and any intervening claims, and recite additional features

which further distinguish these claims from the cited references. Therefore, dependent claims 2-6, 9-11, 13, 15, 18,19, 21, 23 and 26 are also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claims 2-6, 9-11, 13, 15, 18,19, 21, 23 and 26 as being anticipated by Duran. Applicants further respectfully request reconsideration of the rejection of claims 1-6, 9-11, 13, 15, 18-19, 21, 23 and 26.

With respect to the rejection of claim 39 over Duran under 35 U.S.C. 102(b), Applicants respectfully submit that Duran does not teach every element of claim 39, and therefore fails to anticipate claim 39.

The Examiner states that a portion of the reinforcement element 20 is attached downstream from the valve. As discussed in connection with claim 1 above, Duran's "reinforcement element" is actually an open cage frame 20 that is disposed in the central portion of the conduit 28 so that the frame is not circumferentially attached proximate one end of the prosthetic conduit, as required by the instant amendment. Claim 39 sets forth a prosthesis that includes a reinforcement element and a prosthetic conduit wherein the inventive reinforcement element is circumferentially attached proximate one end of the prosthetic conduit and downstream of the valve. Thus, Duran does not disclose all elements of claim 39, and therefore, Duran fails to anticipate claim 39.

Applicants respectfully request withdrawal of the rejection of claim 39 as being anticipated by Duran. Applicants further respectfully request reconsideration of the rejection of claim 39.

Regarding claim 42, Applicants respectfully submit that Klostermeyer does not teach every element of claim 42, and therefore fails to anticipate claim 42.

The Examiner states that claim 42 is clearly anticipated by Figure 3 of Klostermeyer.

Klostermeyer sets forth a prosthetic device that has a valve section 14 combined with a graft section 12. The proximal end 60, or inflow edge, of the graft section 12 is in communication with the valve section 14. The proximal end 60 of the graft section 12 is narrower than the wider tubular portion 18 of the graft section. This diameter differential is accommodated through use of a smooth taper 62 connecting the narrower portion with the wider tubular portion 18. The walls of the wider tubular portion 18 are corrugated 59. (Figures 2 and 3, p. 4, lines 36-38.) Thus, the basic shape of the graft section 12 disclosed by Klostermeyer is a cone shaped tubular structure with corrugated edges.

Claim 42 of the present invention states that a prosthesis comprises a first prosthetic conduit section with a generally cylindrical section and a second integral prosthetic conduit section comprising a prosthetic valve. The inflow edge of the first conduit section is configured for attachment to the outflow edge of the second conduit section.

Thus, claim 42 claims the first conduit section as being cylindrical. A cylinder is the surface traced by a straight line moving parallel to a fixed straight line and intersecting a fixed planer closed curve. (See Merriam-Webster's Dictionary Collegiate 10<sup>th</sup> Edition 1993, p. 288). The edge surfaces of Klostermeyer's tubular graft section 18 is not comprised of parallel straight lines. Instead, the tubular graft section is corrugated. In addition, the proximal portion of the graft section is formed using a taper. Thus, the general longitudinal sectional shape of Klostermeyer's graft section is one of a corrugated cone shaped tube, not a cylinder as claimed by Applicants. Klostermeyer

does not disclose the cylindrical first conduit section and, as a result, does not anticipate claim 42.

Applicants respectfully request withdrawal of the rejection of claim 42 as being anticipated by Klostermeyer.

Dependent claim 44 which depends from independent claim 42 was also rejected under 35 U.S.C. §102(b) as being anticipated by Klostermeyer. While Applicants do not acquiesce with the particular rejection to this dependent claim, it is believed that this rejection is moot in view of the remarks made in connection with independent claim 42. This dependent claim includes all of the limitations of the base claims and any intervening claims, and recites additional features which further distinguish this claim from the cited references. Therefore, dependent claim 44 is also in condition for allowance.

Applicants respectfully request withdrawal of the rejection of claim 44 as being anticipated by Klostermeyer. Applicants further respectfully request reconsideration of the rejection of claims 42 and 44.

Regarding claim 48, Applicants respectfully submit that Fogarty does not teach every element of claim 1, and therefore fails to anticipate claim 1.

The Examiner states that Figure 3 of Fogarty anticipates claim 48.

Fogarty sets forth an intraluminal prosthesis that is assembled from prosthetic modules. Each module has an interface and an element for engaging and/or sealing two modules together at the interfaces. (See Fig. 3). For example, Figs 3B and 3C illustrate the use of barbs to seal modules together. Figure 3D illustrates the use of a helical winding for threaded attachment of adjacent modules.

In contrast to Fogarty's engaging and sealing element, inventive claim 48 comprises a reinforcement element that is circumferentially attached to the prosthetic conduit proximate to the outflow edge. Moreover, Fogarty's engaging and sealing element is disposed at the junction of two prosthetic modules, not proximate to the conduit's outflow edge as claimed by Applicants.

Fogarty does not disclose a reinforcement element circumferentially attached to the prosthetic conduit proximate to the outflow edge and, as a result, does not anticipate claim 48.

Applicants respectfully request withdrawal of the rejection of claim 48 as being anticipated by Fogarty. Applicants further respectfully request reconsideration of the rejection of claim 48.

On page 3 of the Office Action, claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duran in view of Lapeyre, et al (US 6,068,657). Applicants respectfully submit that neither reference, nor the combination thereof, teaches or suggests every element of claim 14, and therefore fails to anticipate claim 14. Applicants respectfully traverse this rejection.

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicants respectfully traverse the rejection since the prior

art fails to disclose all the claim limitations and there would be no motivation to combine the references as proposed by the Examiner.

Claim 14 depends from claim 13 which, in turn, depends from independent claim 1. As discussed at length above in connection with claim 1, Duran fails to meet all limitations of claim 1 for a variety of reasons, including that Duran does not have an expanded section terminating at an edge as in Applicants' claim 1, and that Duran's expandable conduit section does not read on the inventive expanded conduit section. Lapeyre fails to remedy the deficiencies of Duran. Lapeyre simply discloses a prosthetic valve which fails to cure the deficiencies of Duran to meet the limitations of claim 1 relating to the conduit. As a result, neither Duran nor Lapeyre teach or suggest a prosthetic valve connected to the expanded section as claimed in dependent claim 13. Thus, neither reference teaches or suggests a prosthetic valve comprising a rigid leaflet connected to an orifice ring wherein the prosthetic valve is connected to the expanded section as claimed in dependent claim 14.

For at least these reasons, Applicants submit that the proposed combination of references fails to disclose every limitation in claims 1 and its dependent claim 13. Claim 14 depends from claim 13. It is believed that the rejection of claim 14 is moot in view of the remarks made in connection with independent claim 1 and dependent claim 13.

Applicants respectfully request withdrawal of the rejection of claim 14 under 35 U.S.C. §103(a) as obvious over Duran in view of Lapeyre. Applicants further request reconsideration of claim 14.



In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at (952) 253-4134.

Respectfully submitted,

Altera Law Group, LLC  
Customer No. 22865

Date: July 6, 2004

By:

Hallie A. Finucane  
Hallie A. Finucane  
Reg. No. 33,172  
HAF/MAK/mar